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| 09/997,895      | 11/30/2001  | David Samuel Cohen   | 111465.127          | 4229             |

20995 7590 06/30/2004

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| EXAMINER |
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SIEFKE, SAMUEL P

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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,895

Applicant(s)

COHEN, DAVID SAMUEL

Examiner

Samuel P Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Election of species 6/14/04.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.  
4a) Of the above claim(s) 1-10, 28, 29 and 36-57 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 11-27 and 30-35 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 44-57, drawn to an optical bio-disc , classified in class 422, subclass 72.
- II. Claims 11-27, 30-35, drawn to an optical bio-disc, classified in class 422, subclass 72.
- III. Claims 28, 29, drawn to an optical bio-disc drive motor, classified in class 422, subclass 82.05.
- IV. Claims 36-39, 43, drawn to a rotatable disc, classified in class 422, subclass 68.1.
- V. Claim 40, drawn to method for separating components in a sample, classified in class 436, subclass 177.
- VI. Claims 41, 42, drawn to an optical disc, classified in class 422, subclass 72.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Group II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed

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does not require the particulars of the subcombination as claimed because the embodiment can be used for premeasured samples. There is no need for collection of unused sample if the sample size is predetermined and then added in a predetermined fashion. The subcombination has separate utility such as analyzing samples in sample that has excess sample added to the sample input or starting point. The excess fluid is drained to a waste chamber so that a certain sample volume can analyzed.

Inventions Group II and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the assay region can have a reaction that does not need electromagnetic radiation, a reaction dye can be used so that a color change is detected. The subcombination has separate utility such as detecting electromagnetic radiation reactions in a sample.

Inventions Group IV and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the optical disc does not need a motor to turn the disc, it can be done by hand. The

subcombination has separate utility such as delivering precise spin control to a rotational platform.

Inventions Group V and Group VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced by hand. An operator can spin a rotatable disc by hand.

Inventions Group IV and Group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the embodiment can be used to separate a blood sample and not analyze the sample. The subcombination has separate utility such as separating and analyzing a blood sample.

Inventions Group I, II, IV, VI and Group III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the optical

disc does not need a motor to turn the disc, it can be done by hand. The subcombination has separate utility such as delivering precise spin control to a rotational platform.

Inventions Group I, II, IV, VI and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, rotating the disc one time to separate the sample particles.

Inventions Group V and Group III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process can be practiced by hand, rotating the disc by hand.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Drew Hamilton on June 14 a provisional election was made with traverse to prosecute the invention of Group II, claims 11-27 and 30-35. Affirmation of this election must be made by applicant in replying to this

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Office action. Claims 1-10,28,29, 36-57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **11-27, 30-35** are rejected under 35 U.S.C. 102(e) as being anticipate by Kellogg et al. (USPN 6,063,589).

Kellogg discloses a method and apparatus for performing microanalytic analyses on a platform by rotation, thereby utilizing the centripetal forces resulting from rotation of the platform to motivate fluid movement through microchannels embedded in the microplatform. Kellogg discloses an optical bio-disc that comprises a substrate (col. 8, lines 6-38) having encoded information being readable by a disc drive assembly to control rotation of the disc (col. 8, line 37-col. 9, line 20); an antechamber (fig 6a-k; entry port 301); a separation chamber in fluid communication with the antechamber (302; metering capillary allow extra sample to over flow, which separates the sample volume); a metering chamber in fluid communication with the separation tube (303; fluid chamber is connect to the metering chamber and also is provided with a overflow line 304 for

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metering); an assay zone in fluid communication with the metering chamber so that when a sample is deposited in the antechamber and a rotation is applied, a metered amount of a liquid component is moved to the assay zone (col. 17, lines 5-21). The assay chamber includes optical detection of the reaction that occurs in the assay (col. 14, lines 6-35; col. 17, lines 5-21). With regards to claim 14, a disk drive is not claimed, and is not attributed patentable weight, even though Kellogg teaches a read head (col. 14, lines 6-34; col. 9, lines 16-20). Throughout Kellogg there are multiple embodiment which cover all the limitations of claimed subject matter in the instant application. The above embodiment further comprises a waste chamber (306) that is in fluid communication with both the metering chamber (fig. 6a-k). With respect to claims 16-27 and 30-35, it is noted that Applicant recites limitation on the manner in which the biodisk is used. Such limitations are not attributed patentable weight in claims to the device. It is also noted that Kellogg teaches a process in which incorporates the steps recited in these claims. Kellogg discloses that samples to be used in this apparatus comprise blood, plasma, serum, lymph, saliva, tears, cerebrospinal fluid, urine, sweat, plant and vegetable extracts, semen and ascites fluid and does not limit just to these specific examples (col. 6, lines 1-6). Kellogg also discloses a process of using an optical biodisc for separating, metering and analyzing a biological sample (col. 12, line 1 –col. 14, line 38). Kellogg imparts a first rotation to the disc whereby the fluid flows into the metering chamber while excess fluid flows to overflow chamber, a second rotation is imparted on the disc where the fluid in the metering chambers flows to the fluid chamber. Then analysis of the components in the sample are analyzed (col. 14, lines 6-34).



### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



June 24, 2004

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700